

EPA SCIENTIFIC ADVISORY COMMITTEE ON CHEMICALS

CHARGE TO THE PANEL – ASBESTOS

As amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, the Toxic Substances Control Act (TSCA), requires the U.S. Environmental Protection Agency (EPA) to conduct risk evaluations on existing chemicals. In December of 2016, EPA published a list of the initial ten chemical substances that are the subject of the Agency's chemical risk evaluation process ([[HYPERLINK "https://www.federalregister.gov/documents/2016/12/19/2016-30468/designation-of-ten-chemical-substances-for-initial-risk-evaluations-under-the-toxic-substances" \h \]](https://www.federalregister.gov/documents/2016/12/19/2016-30468/designation-of-ten-chemical-substances-for-initial-risk-evaluations-under-the-toxic-substances)), as required by TSCA. Asbestos is one of the first ten chemical substances and the fourth? of the ten to undergo a peer review by the Science Advisory Committee on Chemicals (SACC). In response to this requirement, EPA has prepared and published a draft risk evaluation for asbestos which solicited comments from the public and incorporated them as appropriate in the documents considered in this review. Asbestos is a carcinogen that is used in particular areas of the chemical, oil, and automotive industries and in articles.

The draft risk evaluation contains the following components:

- Discussion of chemistry and physical-chemical properties.
- Characterization of uses/sources.
- Environmental release assessment
- Occupational exposure assessment
- Environmental, and consumer exposure assessment
- Environmental hazard assessment
- Human health hazard assessment
- Risk characterization. TBD
- Risk determination. TBD
- A detailed description of the systematic review process developed by the Office of Pollution Prevention and Toxics to search, screen, and evaluate scientific literature for use in the risk evaluation process.

The focus of this meeting is to conduct the peer review of the Agency's draft risk evaluation of asbestos. At the end of the peer review process, EPA will use the reviewers' comments/recommendations, as well as public comment, to finalize the risk evaluation.

CHARGE QUESTIONS:

1. Content and Organization:

EPA's Final Rule, [[HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h](https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf)] [[HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h](https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf)]([[HYPERLINK "https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act" \h](https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act)]) stipulates the process by which EPA is to complete risk evaluations under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. To that end, EPA has completed a draft risk evaluation for asbestos.

As part of this risk evaluation for asbestos, EPA evaluated potential environmental, occupational, and consumer exposures. The evaluation considered reasonably available information, including manufacture, use, and release information, and physical-chemical characteristics. It is important that the information presented in the risk evaluation and accompanying documents are clear and concise and describe the process in a scientifically credible manner.

Please comment on the overall content, organization, and presentation of the draft risk evaluation of asbestos. Please provide suggestions for improving the clarity of the information presented in the documents.

[NOTE: Links to literature flow diagrams, appendices and supplemental files will be provided when they become available]

2. Systematic Review:

The Toxic Substances Control Act (TSCA) requires that EPA use data and/or information in a manner consistent with the “best available science” and that EPA base decisions on the “weight of the scientific evidence”. The EPA's Final Rule, [[HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h](https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf)] [[HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf" \h](https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14337.pdf)]([[HYPERLINK "https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act" \h](https://www.federalregister.gov/documents/2017/07/20/2017-14337/procedures-for-chemical-risk-evaluation-under-the-amended-toxic-substances-control-act)]), defines “best available science” as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). The Final Rule also defines the “weight of the scientific evidence” as a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

To meet these scientific standards, EPA applied systematic review approaches and methods to support the draft risk evaluation of asbestos. Information on the approaches and/or methods is described in the draft risk evaluation as well as the following documents:

- [[HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations"](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/application-systematic-review-tsca-risk-evaluations)]
- [[HYPERLINK "https://www.epa.gov/sites/production/files/2017-06/documents/14-dioxane_lit_search_strategy_053017.pdf"](https://www.epa.gov/sites/production/files/2017-06/documents/14-dioxane_lit_search_strategy_053017.pdf)]
- Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document, [[HYPERLINK "https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0736"](https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0736)]
- Asbestos [[HYPERLINK "https://www.epa.gov/sites/production/files/2018-06/documents/14-dioxane_problem_formulation_5-31-18.pdf"](https://www.epa.gov/sites/production/files/2018-06/documents/14-dioxane_problem_formulation_5-31-18.pdf)]

Please comment on the approaches and/or methods used to support and inform the gathering, screening, evaluation, and integration of information used in the draft risk evaluation of asbestos. Please also comment on the clarity of the information as presented related to systematic review and suggest improvements as warranted.

3. Occupational Exposure:

Workers and occupational non-users may be exposed to chrysotile asbestos when workers perform activities associated with several conditions of use. These conditions of use pertain to:

- Asbestos diaphragms used in the chlor-alkali industry
- Asbestos-containing sheet gaskets
- Oil field brake blocks
- Aftermarket automotive brakes and linings
- Friction products for other vehicles and equipment

The principle approach EPA used to estimate occupational exposures was reviewing and interpreting monitoring data, whether documented in the peer-reviewed literature or provided by industry.

Please comment on the reasonableness of (1) the estimation methods and approaches used for occupational exposure assessment and (2) the estimated worker exposure concentrations used in the risk evaluation. Provide specific suggestions or recommendations for alternative approaches, estimation methods, or information sources that EPA should consider for improving the occupational exposure assessment.

4. Consumer Exposure

Please comment on the reasonableness of the estimation methods and approaches used for consumer exposure assessment and provide any specific suggestions or recommendations for alternative approaches, estimation methods or information that should be considered by the Agency for improving the consumer exposure assessment.

- a. Please comment on EPA's approach to use a tiered method for identify brake exposure studies that have a higher and/lower potential for risk.
- b. Please comment on EPA's approach to use activity patterns to estimate doses.

- c. Please comment on EPA's approach to characterize variability and uncertainty for exposure estimates.

5. *Environmental Exposure:*

- a. Information identified by the EPA to characterize environmental hazards posed by chrysotile asbestos only quantified the effects of chronic exposure. Although there is limited data available to characterize effects caused by acute exposures, based on the physical-chemical properties of asbestos (i.e., insoluble fiber), ecotoxicity effects from acute exposures of chrysotile asbestos are not expected. Please comment on EPA's use of physical chemical properties to determine the ecotoxicity hazards from acute exposures.
- b. The range of aquatic ecotoxicity concern posed by chrysotile asbestos from chronic exposures were based on only 4 acceptable studies from the same author. Please comment on EPA's approach of determining a range of concern due to the limited available ecotoxicity hazard data.
- c. EPA was unable to calculate a risk quotient for ecotoxicity due to limited environmental releases data for asbestos. Please comment on EPA's determination that there is no unreasonable risks to ecological receptors from acute and chronic exposures of chrysotile asbestos in the relevant conditions of use.

6. *Human Health Hazard* *To be added*

7. *Risk Characterization / Risk Determination:* *To be added*